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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/866,925 | 05/30/2001 | Richard J. Feldmann | 3124-Z | 5146 |

7590

12/09/2005

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EXAMINER

BRUSCA, JOHN S

ART UNIT PAPER NUMBER

1631

DATE MAILED: 12/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/866,925
Filing Date: May 30, 2001
Appellant(s): FELDMANN, RICHARD J.

Jim Zegeer
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 22 June 2005 and the amended appeal brief filed 05 August 2005 appealing from the Office action mailed 23 September 2004.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

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(8) Evidence Relied Upon

Mattick, Non-coding RNAs: the architects of eukaryotic complexity. EMBO reports Vol. 21, No. 11, pages 986-991, especially page 986 (2001)

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) Quantity of experimentation: In order to practice the claimed invention one of skill in the art must identify and use a connectron to predict regulation of gene expression. For the reasons discussed below, there would be an unpredictable amount of experimentation required to

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practice the claimed invention.

b) The amount of direction or guidance presented: The claimed invention is a method of identification of sequences that have a connectron relationship and act to modulate gene expression. On page one, the specification defines connectrons as a tetradic structure between two sequences in an RNA transcript of a genomic sequence and two sequences in double stranded genomic DNA. Figure 4 depicts a connectron. The specification speculates without evidence on pages 1-3 that triple-stranded structures will form between RNA and double stranded DNA in chromatin where connectron symmetries are identified. The specification provides guidance to identify connectron symmetries in genomic sequences on pages 31-34. The specification does not provide detailed guidance to use identified connectron symmetries because the specification does not show whether or not connectrons as depicted in figure 4 form within cells or have an effect on gene expression.

c) The presence or absence of working examples: The specification provides working examples of identification of connectron symmetries by computer-mediated searching of genomic sequences in pages 35-188. However, the claimed method of identifying sequences that control gene expression has not been reduced to practice. The specification does not provide working examples of using identified connectron symmetries to predict effects on gene expression. The specification does not provide experimental evidence that connectrons form within cells or that connectron symmetries identified by computer searches allow for prediction of modulation of gene expression of genes that have connectron symmetries.

d) The nature of the invention: The nature of the invention, gene expression control, is complex.

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e) The state of the prior art: One of skill in the art, after reading the specification, would not know that connectron symmetries identified by computer-mediated searches of genomic sequences would allow for prediction of gene expression of genes that have connectron symmetries. The specification does not provide experimental evidence that connectron symmetries cause modulation of gene expression. Neither the prior art nor post-filing art shows connectrons. Mattick (published in 2001, one year after the effective instant filing date) reviews effects of RNA molecules on gene regulation. Mattick does not show connectrons as defined in the instant specification.

f) The relative skill of those in the art: The skill of those in the art of gene expression is high.

g) The predictability of the art: The predictability of the relationship of connectron symmetries and gene expression is unknown in the prior art and is not described in the instant specification.

h) The breadth of the claims: The claims are broad in that they are drawn to identification of connectron symmetries whose relationship to gene expression is not established.

The skilled practitioner would first turn to the instant specification for guidance in using the claimed invention. However, the specification lacks any evidence that connectron symmetries are related to gene expression. As such, the skilled practitioner would turn to the prior art for such guidance, however the prior art does not discuss connectron symmetries. Finally, said practitioner would turn to trial and error experimentation to determine a relationship between connectron symmetries and gene expression. Such amounts to undue experimentation.

(10) Response to Argument

The appellant states in his arguments that the declarants James Oberthaler and Richard Pastor show that one of skill in the art is enabled to determine sequences that have the claimed relationship to genomic sequences. It is agreed that sequences that have the claimed relationship to genomic sequences could be determined. However the appellant has failed to provide evidence that the claimed methods could be used to predict regulation of gene expression. The specification concedes on page 29 in paragraph 113 that “The physical existence and lifetimes of the connectrons must be proved by molecular biological experimentation.” In discussing this section of the specification on page 6 of the Appeal Brief, the appellant concedes that the physical experimentation is quite distinct from the computational identification of connectron symmetries. The declarations of Oberthaler and Pastor concentrate on enablement for identification of connectron symmetries, which has never been contested by the Office. On page 7 of the Appeal Brief the appellant points to a statement in the Oberthaler declaration that RNA molecules would seek out and bind target DNA and shield the DNA from transcription. This is mere speculation by the declarant that is not supported by scientific evidence.

Although some of the exemplified RNA molecules may exist as transcripts in cells, their role in regulation of gene expression has not been observed. In the absence of a showing by the appellant in the specification or subsequent declarations, or by the prior art, that the claimed methods can be used to predict gene expression the specification does not enable use of the claimed methods.

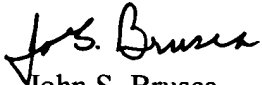
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(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

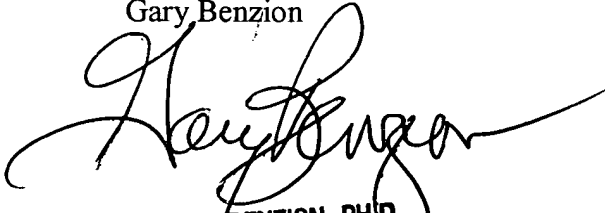
For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

 1 December 2005
John S. Brusca

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